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10/657,685	09/08/2003	Allan H. Conney	RU-0191	1261

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/657,685

Applicant(s)

CONNEY, ALLAN H.

Examiner

Cybill Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-8 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/9/04; 7/26/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

***Detailed Action***

The following is responsive to the preliminary amendment received Dec. 8, 2003.

Claims 1-8 are presented for prosecution on the merits.

***Information Disclosure Statement(s)***

Applicant's information disclosure statements received Feb. 9, 2004 and Jul. 26, 2004 have been considered. Please refer to Applicant's copies of the 1449s submitted herewith.

***Claim Objection(s)***

1. Claims 5-6 are objected to because of the following informalities: in claims 5 and 6, "paclitaxol" should be cancelled and replaced with --paclitaxel--. Appropriate correction is required.

***Claim Rejection(s)—35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Zheng et al., Oncology Research, Vol. 12, pages 419-427.

Zheng et al. disclose the synergistic effects of a combination composition comprising all-trans retinoic acid and 12-O-tetradecanoylphorbol-13-acetate (TPA).

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Zheng et al. teach that the combination of these compounds results in a synergistic effect against HL-60 leukemia cells. Please see the abstract; Fig. 2; page 424; Table 1.

With respect to the intended use of claims 1-2, "if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997).

Please see MPEP 2111.02.

Since the prior art combination composition would be capable of performing the claimed intended use, the prior art anticipates the claims.

***Claim Rejection(s)—35 USC 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant et al., WO 02/22133 A1 and Powell et al. in view of Farmer et al., 6,005,007 and Sporn et al., 5,821,254.

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Grant et al. disclose a method of promoting apoptosis in cancer cells, the method comprising administering an effective amount of an agent that induces cellular differentiation and a cyclin dependent kinase inhibitor. The specific agents for inducing cellular differentiation include PMA, i.e. 12-O-tetradecanoylphorbol-13-acetate and retinoids such as all trans retinoic acid. These agents may be combined with the cyclin dependent kinase inhibitors to induce apoptosis in prostate cancer, for example. Please see page 4.

Powell et al. disclose that 12-O-tetradecanoylphorbol-13-acetate induces apoptosis in androgen-sensitive prostate cancer cells. Please see the abstract.

Grant et al. and Powell et al. do not specifically disclose treating prostate cancer in a patient in need thereof by administering to the patient a composition comprising PMA and a retinoid; however, the Examiner refers to (1) Farmer et al., which disclose a method for treating cancer, such as prostate cancer, by administering an effective amount of a retinoid compound (please see the abstract; col. 7, lines 4-8) and (2) Sporn et al., which disclose the use of 9-cis-retinoic acid compounds in the treatment of cancers such as prostate cancer (please see the abstract; col. 4, line 1-28).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Grant and Powell to treat prostate cancer by administering a composition containing a combination of PMA and the retinoids of Farmer and Sporn because one of ordinary skill in the art would reasonably expect the additive effect of the two compounds to be effective in inhibiting the growth of prostate cancer cells thereby treating the patient suffering from prostate cancer.

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4. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grant et al., WO 02/22133 A1 and Powell in view of Broder et al., 6,395,770.

Grant et al. as applied above.

Powell et al. teach that 12-O-tetradecanoylphorbol-13-acetate induces apoptosis in androgen-sensitive prostate cancer cells. Please see the abstract.

Grant and Powell do not disclose a method for treating prostate cancer by administering a composition comprising 12-O-tetradecanoylphorbol-13-acetate (PMA) in combination with paclitaxel. Yet, the Examiner turns to Broder et al., which disclose a method of treating cancers such as prostate cancer, by orally administering to a patient in need thereof an effective amount of paclitaxel. Please see col. 10, lines 16-20.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods of Grant and Powell to administer a composition containing a combination of 12-O-tetradecanoylphorbol-13-acetate and paclitaxel because one of ordinary skill in the art would reasonably expect the combination of the two compounds to effectively treat prostate cancer. Such a modification would have been motivated by the reasonable expectation that the apoptosis-inducing activity of 12-O-tetradecanoylphorbol-13-acetate and the cytotoxic activity of paclitaxel combined would effectively inhibit and thereby treat prostate cancer.

Applicant is advised that should claims 1 and 2 as well as claims 5 and 6 be found allowable, claims 1-2 and 5-6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else

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are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 1 and 2 as well as claims 5 and 6 are identical in scope.

### ***Conclusion***

Claims 1-8 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

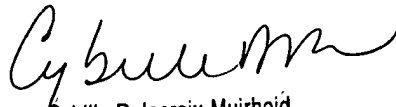
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CDM

March 6, 2005



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600